K051406

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AUG 1 - 2005

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: May 26, 2005

Applicant: Futura Biomedical
990 Park Center Drive
Vista, CA 92081

Telephone: 760-599-1670
Fax: 760-599-1675
Contact: Louise M. Focht

Device Name:	Filler, Bone Void, Calcium Compound
Device Trade Name:	OsteoCure Resorbable Bead Kit Osteo Cure Injectable Graft Kit
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	21 CFR 888.3045
Product Code:	87 MQV
Predicate Device:	Biogeneration, ProFusion Bone Graft Substitute Kits, K031838, K973704, Wright Medical K010532, K024336
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description:

OsteoCure Resorbable Bead Kit and OsteoCure Injectable Graft Kit consist of pre-measured surgical grade calcium sulfate, pre-measured mixing solution, and the tools necessary to mix the components into a paste. These products are provided sterile for single patient use. When mixed according to directions, the OsteoCure Kits produce biodegradable, radiopaque paste/molded beads that resorb in approximately 30-60 days, when used according to labeling.

After the powder is hydrated using all of the mixing solution supplied in each kit, the resultant paste can be injected, digitally packed into the bone void to cure in-situ; or molded into solid implants that are gently packed into non-load bearing voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The implants provide a bone void filler that resorbs and is replaced with bone during the healing process.

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Materials:

The materials used for the OsteoCure Kits are substantially equivalent to Biogeneration, Profusion Bone Graft Substitute Kit and Wright Medical OsteoSet.

Indications for Use:

The paste made with OsteoCure is intended to be injected, digitally packed into bone voids or gaps; or molded into solid pellets that are gently packed into bone voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system (i.e. long bones, extremities, spine and pelvis). The bone voids or gaps may be either surgically created or result from traumatic injury. The device provides a bone void filler that resorbs and is replaced with bone during the healing process.

OsteoCure paste cured in situ provides a bone void or gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary scaffold and is not intended to provide support during the healing process.

OsteoCure Kits are provided sterile for single use only. Because the device is biodegradable and biocompatible, it may be used at an infected site.

Comparison to Predicate Device:

Technological Characteristics:

The OsteoCure Kits have the equivalent chemical composition and the technological characteristics as the predicate device.

Performance data:

Testing demonstrated that the performance of the OsteoCure Kits are substantially equivalent to the performance of the predicate device.

Summary:

The intended use, material composition, and design features of the OsteoCure Injectable Graft Kit paste cured in situ and OsteoCure Resorbable Bead Kits are substantially equivalent to the intended use, material composition and design features of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 - 2005

Ms. Louise M. Focht
Futura Biomedical
990 Park Center Drive, Suite H
Vista, California 92081

Re: K051406
Trade/Device Name: OsteoCure Resorbable Bead Kit
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device.
Regulatory Class: II
Product Code: MQV
Dated: May 26, 2005
Received: May 31, 2005

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051406

Device Name: OsteoCure Resorbable Bead Kit

Indications for Use:

The paste made with OsteoCure is intended to be injected, digitally packed into bone voids or gaps; or molded into solid pellets that are gently packed into bone voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system (i.e. long bones, extremities, spine and pelvis). The bone voids or gaps may be either surgically created or result from traumatic injury. The device provides a bone void filler that resorbs and is replaced with bone during the healing process.

OsteoCure paste cured *in-situ* provides a bone void or gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary scaffold and is not intended to provide support during the healing process.

OsteoCure Kits are provided sterile for single use only. Because the device is biodegradable and biocompatible, it may be used at an infected site.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051406